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COOLEY GODWARD LLP
STEPHEN P. SWINTON (106398)
JAMES DONATO (146140)
PATRICK M. MALONEY (197844)
4365 Executive Drive, Suite 1100
San Diego, CA 92121-2128
Telephone: (858) 550-6000
Facsimile: (858) 453-3555

R. WILLIAM BOWEN, JR. (102178)
GEN-PROBE INCORPORATED
10210 Genetic Center Drive
San Diego, CA 92121-4362
Telephone: (858) 410-8918
Facsimile: (858) 410-8637

Attorneys for Plaintiff
Gen-Probe Incorporated

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED,

Plaintiff,

v.

VYSIS, INC.,

Defendant.

No. 99cv2668 H (AJB)

**GEN-PROBE INCORPORATED'S OBJECTIONS
AND RESPONSES TO VYSIS, INC.'S SECOND SET
OF INTERROGATORIES**

PROPOUNDING PARTY: DEFENDANT VYSIS, INC.
RESPONDING PARTY: PLAINTIFF GEN-PROBE INCORPORATED
SET NUMBER: TWO (2)

Pursuant to Federal Rule of Civil Procedure 33, Plaintiff Gen-Probe Incorporated ("Gen-Probe") responds as follows to Defendant Vysis, Inc.'s ("defendant") second set of interrogatories:

I. GENERAL RESPONSES.

1. Gen-Probe's response to defendant's second set of interrogatories is made to the best of Gen-Probe's present knowledge, information, and belief. Said response is at all times subject to such additional or different information that discovery or further investigation may disclose and,

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1 while based on the present state of Gen-Probe's recollection, is subject to such refreshing of
2 recollection, and such additional knowledge of facts, as may result from Gen-Probe's further
3 discovery or investigation. Gen-Probe reserves the right to make any use of, or to introduce at any
4 hearing and at trial, information and/or documents responsive to defendant's first set of
5 interrogatories but discovered subsequent to the date of this response, including, but not limited to,
6 any such information or documents obtained in discovery herein.

7 2. To the extent that Gen-Probe responds to defendant's interrogatories by stating that
8 Gen-Probe will provide information and/or documents which Gen-Probe, any other party to this
9 litigation, or any other person or entity deems to embody material that is private, business
10 confidential, proprietary, trade secret, or otherwise protected from disclosure pursuant to Federal
11 Rule of Civil Procedure 26(c)(7), Federal Rule of Evidence 501, California Evidence Code section
12 1060, or California Constitution, article I, section 1, or any like or similar provision of law of any
13 jurisdiction Gen-Probe will do so only upon the entry of an appropriate protective order against the
14 unauthorized use or disclosure of such information.

15 3. Gen-Probe reserves all objections or other questions as to the competency, relevance,
16 materiality, privilege or admissibility as evidence in any subsequent proceeding in or trial of this or
17 any other action for any purpose whatsoever of Gen-Probe's responses herein and any document or
18 thing identified or provided in response to defendant's interrogatories.

19 4. Gen-Probe reserves the right to object on any ground at any time to such other or
20 supplemental interrogatories as defendant may at any time propound involving or relating to the
21 subject matter of these interrogatories.

22 **II. GENERAL OBJECTIONS.**

23 1. Gen-Probe makes the following general objections, whether or not separately set forth
24 in response to each interrogatory, to each instruction, definition, and interrogatory made in
25 defendant's first set of interrogatories:

26 2. Gen-Probe objects generally to interrogatories 3 through 9, insofar as they seek
27 information or production of documents protected by the attorney-client or the attorney work
28 product privilege. Such information or documents shall not be provided in response to defendant's

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1 advance at trial before the completion of investigation and discovery. Gen-Probe also objects that
2 to the extent this request seeks documents relating to products other than Gen-Probe's NAT test
3 kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not
4 reasonably calculated to lead to the discovery of admissible evidence. Without waiving, and
5 subject to, the foregoing objections, Gen-Probe responds as follows:

6 No Gen-Probe product uses "target capture" or "amplification" within the meaning of those
7 terms as used in the properly construed claims of the '338 patent. Gen-Probe understands the term
8 "product" as used in this interrogatory to mean a product that has been the subject of a commercial
9 sale and understands the term "product" to exclude nucleic acid tests that have been transferred for
10 use in connection with clinical trials. Subject to all of the foregoing, Gen-Probe responds that its
11 nucleic acid tests for the detection of HIV and hepatitis C virus ("HCV") in donated blood and
12 blood products use a form of target capture and a form of amplification that are not disclosed or
13 claimed in the '338 patent. Between January 1, 1999 and March 30, 2000 Gen-Probe had sold kits
14 for the detection of HIV and HCV (in 5,000-test kits and 1,000-test kits) to Chiron Corporation,
15 Bayer Corporation, and Chugai Diagnostic Sciences Co., Ltd. These products were manufactured
16 at 10210 Genetic Center Drive, San Diego, California and at 10808 Willow Court, San Diego,
17 California. Gen-Probe believes that the HIV/HCV tests are not encompassed by the properly
18 construed claims of the '338 patent for the reasons previously set forth in response to Interrogatory
19 No. 2.

20 **INTERROGATORY NO. 5:**

21 Identify each opinion, report, study, or search results, written or oral, received by,
22 requested by, or known to Gen-Probe relating to the validity, scope, or enforceability of one or
23 more claims of the '338 patent or to the infringement or non-infringement of one or more claims of
24 the '338 patent by any of the products identified in Interrogatory No. 4 including but not limited to
25 Gen-Probe's NAT test kits for use in detecting HCV or HIV.

26 **RESPONSE TO INTERROGATORY NO. 5:**

27 Gen-Probe incorporates into this response each of the foregoing General Responses and
28 General Objections as if fully set forth herein. Gen-Probe also objects that to the extent this

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1 request seeks documents relating to products other than Gen-Probe's NAT test kits for use in
2 detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably
3 calculated to lead to the discovery of admissible evidence. Without waiving, and subject to, the
4 foregoing objections, Gen-Probe declines to respond on the grounds of the attorney-client privilege
5 and attorney work product.

6 **INTERROGATORY NO. 6:**

7 List separately and identify: licenses, agreements, contracts or undertakings, either foreign
8 or domestic, entered into by Gen-Probe with third parties, including documents relating to any
9 contemplated licenses, agreements, contracts or undertakings, either foreign or domestic, relating
10 to each product identified in Interrogatory No. 4, including but not limited to Gen-Probe's NAT
11 test kits for use in detecting HCV or HIV.

12 **RESPONSE TO INTERROGATORY NO. 6:**

13 Gen-Probe incorporates into this response each of the foregoing General Responses and
14 General Objections as if fully set forth herein. Gen-Probe also objects that to the extent this
15 request seeks documents relating to products other than Gen-Probe's NAT test kits for use in
16 detecting HCV or HIV, the interrogatory is overbroad, unduly burdensome and not reasonably
17 calculated to lead to the discovery of admissible evidence. Without waiving, and subject to, the
18 foregoing objections, Gen-Probe responds as follows:

19 On June 11, 1998, Gen-Probe has entered into an agreement with Chiron Corporation
20 relating to nucleic acid tests for use in blood screening and clinical diagnostics. Chiron
21 subsequently assigned its rights in the clinical diagnostics portion of the agreement to Bayer
22 Corporation

23 **INTERROGATORY NO. 7:**

24 State in detail each factual and each legal basis for Gen-Probe contention that the '338
25 patent is unenforceable, including each unenforceability contention advanced by Gen-Probe in
26 briefing on Vysis' motion for a stay of these proceedings.

27 **RESPONSE TO INTERROGATORY NO. 7:**

28 Gen-Probe incorporates into this response each of the foregoing General Responses and

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1 General Objections as if fully set forth herein. Gen-Probe also objects that to the extent this
2 interrogatory seeks information relating to products other than Gen-Probe's NAT test kits for use
3 in detecting HCV or HIV, the interrogatory is overbroad, unduly burdensome and is not reasonably
4 calculated to lead to the discovery of admissible evidence. Gen-Probe further objects to this
5 interrogatory to the extent that it prematurely seeks the facts and contentions that Gen-Probe will
6 advance at trial before the completion of investigation and discovery. Without waiving, and
7 subject to, the foregoing objections, Gen-Probe will agree to disclose the bases upon which it
8 asserted in its briefing on Vysis' motion to stay that the '338 patent is unenforceable and responds
9 as follows:

10 The '338 patent is unenforceable due to Vysis's inequitable conduct in the prosecution of
11 its applications for the patent, as follows:

12 The patent applicant delayed the prosecution of the applications for the method invention
13 from the filling of the 136,920 application on December 21, 1987 through at least the issuance of
14 the patent on May 12, 1998, a period of 10 1/2 years.

15 In connection with the petition to revive the abandoned 07/944,505 application, the patent
16 applicant misrepresented to the PTO that the '505 application had been *unintentionally* abandoned.

17 The patent applicant failed to maintain consonance with the segregation of the method and
18 device inventions after the filing of applications 944,505 and 648,468, by amending application
19 no. 238,080 to allege that it was a divisional of application no. 400,657.

20 In the December 14, 1998 Request for Certificate of Correction, the patent applicant
21 represented to the PTO that the mistakes identified in the Request were of minor character and
22 resulted from errors made in good faith.

23 In the December 14, 1998 Request for Certificate of Correction, the patent applicant
24 representing to the PTO that the mistakes identified in the Request were first identified after the
25 issuance of the '338 patent and that the so-called "Error 2" had "only recently" been identified,
26 when in fact Error 2 had been identified in 1995 and an amendment requested on March 8, 1995 in
27 the course of the prosecution of application 08/400,657.

28 In the December 14, 1998 Request for Certificate of Correction, the patent applicant

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1 represented to the PTO that the failure to respond to the November 5, 1992 Office Action
2 concerning the '505 application had been inadvertent and that the '505 application had been
3 unintentionally abandoned.

4 The patent applicant failed to maintain consonance with the segregation of the method and
5 device inventions after the filing of applications 944,505 and 648,468, by changing the priority
6 claim of the '338 patent to assert that the '080 application was a continuation of application no.
7 124,826.

8 In the December 14, 1998 Petitions Requesting Entry of Amendment To Abandoned
9 Applications, the patent applicant represented to the PTO that *Sampson v. Commissioner*, 195
10 U.S.P.Q. 136 (D.D.C. 1976), supported the amendments sought in the Petitions.

11 The patent applicant filed the reissue application in March 2000 without advising the PTO
12 of the prior post-issuance amendments and corrections to the '338 patent sought in December 1998
13 and entered thereafter.

14 The patent applicant failed to advise the PTO that the term "amplify" as used in the
15 applications for the '338 patent (and the corresponding reissue application), properly construed,
16 did not include target specific amplification.

17 **INTERROGATORY NO. 8:**

18 Identify all persons with knowledge of any of the facts listed in Gen-Probe's responses to
19 Vysis' interrogatory Nos. 1-7.

20 **RESPONSE TO INTERROGATORY NO. 8:**

21 Gen-Probe incorporates into this response each of the foregoing General Responses and
22 General Objections as if fully set forth herein. Without waiving, and subject to, the foregoing
23 objections, Gen-Probe responds as follows:

24 Peter Shearer; Christine Gritzmacher; Dan Kacian; William Bowen; Henry L. Nordhoff;
25 John Bishop; Norval Galloway, Anthony Janiuk; Charles E. Lipsey; Thomas Ryan; Hon. Ronald
26 Prager; Thomas Banks; Mark Collins; Donald Halbert; Walter King; Jonathan Lawrie; Scott
27 Decker; Sherrol McDonough; Martha Bott; Sharon Bodrug.

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INTERROGATORY NO. 9:

State in detail each factual and each legal basis, other than non-infringement of the '338 patent by Gen-Probe's NAT test kits for detecting HCV or HIV, invalidity of the '338 patent, or unenforceability of the '338 patent, for the statement in paragraph 22 of Gen-Probe's First Amended Complaint for Declaratory Relief and Unfair Competition that "Gen-Probe contends that it has no obligation to make any royalty payments to Vysis with respect to its present products and activities and any contemplated products and activities," if Gen-Probe contends other bases exist.

RESPONSE TO INTERROGATORY NO. 9:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects to this interrogatory to the extent that it seeks prematurely, before the completion of investigation and discovery, the facts and contentions that Gen-Probe will advance at trial. Without waiving, and subject to, the foregoing objections, Gen-Probe will agree to disclose the bases upon which it asserted the allegations of paragraph 22 of the First Amended Complaint and responds as follows:

At this time, Gen-Probe does not contend that it has no obligation to make any royalty payments to Vysis with respect to its present products and activities and any contemplated products and activities on any basis other than invalidity, unenforceability, and the fact that Gen-Probe's products are not encompassed by the properly construed claims of the '338 patent

Dated: June 20, 2000

COOLEY GODWARD LLP
STEPHEN P. SWINTON (106398)
JAMES DONATO (146140)
PATRICK M. MALONEY (197844)

GEN-PROBE INCORPORATED
R. WILLIAM BOWEN, JR. (102178)

By: 
Stephen P. Swinton

Attorneys for Plaintiff
Gen-Probe Incorporated